



Patmont Motor Werks

A Nevada Corporation

P.O. Box 1209

Minden, NV 89423

PH 775/782.0113 FAX 775/783.9004 GOPED.COM

510(K) SUMMARY

K091478

SUBMITTER:

Patmont Motor Werks, Inc.
2220 Meridian Blvd.
Minden, NV 89423
Phone: (775) 782-0113 x.215
Fax: (775) 783-9004

JUN 18 2009

Steven J. Patmont

DATE: May 5th, 2009

NAME OF DEVICE:

Trade Name: Trevair Chair
Classification Name: Manual Wheelchair - Product Code: IOR

PREDICATE DEVICES:

- 1) Per4maX Medical, LLC - Shockwave Suspension Wheelchair - K032123
- 2) Colours - Boing - K945534

INTENDED USE:

The intended use of Trevair Chair is to provide mobility to persons with physical limitations limited to a sitting position. It is intended for indoors and outdoor use by individuals of all ages who are physically challenged. Designed and handcrafted in Minden Nevada, USA, specifically for any individuals who want or need plush suspension at an uncompromising wheel chair weight.

DESCRIPTION OF DEVICE:

Trevair Chair is a self-propelled, rigid frame, mechanical wheelchair consisting of components typical of most manual wheelchairs. It has large rear wheels with push rims for self-propulsion and small front pivoting casters for turning and stability. It is a lightweight, user adaptable, everyday chair for use both indoors and outdoors.

SUBSTANTIAL EQUIVALENCE:

The Trevair Chair is substantially equivalent to the listed predicate devices in its specifications, performance and use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 18 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Patmont Motor Werks, Incorporated
% Mr. Steven J. Patmont
Chief Executive Officer & Owner
2220 Meridian Boulevard
Minden, Nevada 89423

Re: K091478

Trade/Device Name: Trevair Chair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 15, 2009
Received: June 17, 2009

Dear Mr. Patmont:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

Page 2-Mr. Steven J. Patmont

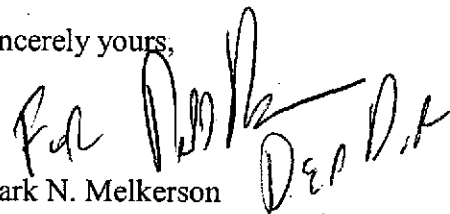
practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Patmont Motor Werks
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INDICATIONS FOR USE

510(K) NUMBER: K091478

DEVICE NAME: Trevair Chair

INDICATIONS OF USE:

The intended use of Trevair Chair is to provide mobility to persons with physical limitations limited to a sitting position. It is intended for indoors and outdoor use.

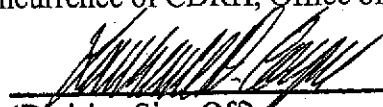
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091478